Section 807.87(h) 510(k) Summary

Section 807.92(a)

(1) DATE OF PREPARATION: July 28, 2000

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990 and 21 CFR 807.92. NovoFine® 31 G x 6 mm needles meet all applicable product and quality control standards for hypodermic single lumen needles products.

SUBMITTER'S NAME AND ADDRESS:

Novo Nordisk Pharmaceuticals, Inc.
100 Overlook Center, Suite 200
Princeton, New Jersey 08540

Contact person: Michael Barbush
Tel: 609-987-5973
Fax: 609-987-3916

(2) NAME OF DEVICE:

Proprietary Name:	NovoFine® 31 G x 6 mm needles
Classification:	Hypodermic single lumen needle
Common or usual name:	Sterile disposable hypodermic needle
Class:	Class II

(3) SUBSTANTIAL EQUIVALENCE

The NovoFine® 31G x 6 mm needle is substantially equivalent to NovoFine® 30G x 8 mm needle, (submitted as part of the NovoPen® 1.5 510(k), #K942159) which was cleared by FDA in April 1995.

Section 807.87(h) 510(k) Summary (continued)

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as supplied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statement related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the court.

(4) DEVICE DESCRIPTION:

The single-pointed Type 304 stainless steel needle is epoxy bonded to a plastic hub (polypropylene) and covered with a plastic inner needle cap (polyethylene). This needle/hub/inner needle cap assembly is placed in a plastic outer container (polyethylene), the open end of which is sealed closed with a laminate seal for subsequent protection. Sterilization (steam or ethylene oxide) will be employed and the product will meet 10^{-6} sterility assurance levels. During use, the laminate seal is peeled away and the exposed needle hub is screwed onto the pen injector device. This exposed needle hub will penetrate the rubber septum of a sterile, parenteral drug product filled into a cartridge (supplied by Novo Nordisk or others). After the inner needle cap is removed, it is ready for subcutaneous injection. The needle assembly is a single-use disposable device.

Section 807.87(h) 510(k) Summary (continued)

(5) INTENDED USE:

The intended use for the modified device remains the same as the predicate device: for use with a pen injector device for the subcutaneous injection of insulin drug products.

(6) TECHNOLOGICAL CHARACTERISTICS:

The NovoFine 31 0.25 x 6mm and the predicate device (NovoFine 30 0.30 x 8mm) has the same technological characteristics. The only difference to the predicate device is to the gauge and size of the needle.

Section 807.92(b)

(1) NON-CLINICAL TESTS PERFORMED:

Performance tests have been performed in compliance with existing international standards and protocols, with data results found equivalent to predicate device.

(2) CLINICAL TESTS SUBMITTED

No tests were done comparing the NovoFine 31 0.25 x 6mm to the predicate device NovoFine 30 0.30 x 8mm.

(3) CONCLUSIONS DRAWN FROM NON-CLINCAL AND CLINICAL TESTS.

Based on the design equivalency and the functional and safety testing, Novo Nordisk had determined that the NovoFine 31 0.25 x 6 mm needles are substantially equivalent to the devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2000

Mr. Michael Barbush
Assistant Director, Regulatory Affairs
Novo Norodisk Pharmaceuticals, Incorporated
100 Overlook Center, Suite 200
Princeton, New Jersey 08540-7810

Re: K002403
Trade Name: NovoFine 31G Disposable Needle
Regulatory Class: II
Product Code: FMI
Dated: November 28, 2000
Received: November 29, 2000

Dear Mr. Barbush:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 801.109 Indication for Use Statement

510(k) Number (if known): K002403

Device Name: NovoFine® 31G x 6 mm needle

Indications for Use: NovoFine® 31G x 6 mm needles are used in conjunction with pen injector delivery devices for insulin drug products.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use_____ OR Over-The-Counter Use ✓

(PART 21 CFR 801.109) (Optional Format 1-2-96)

Patricia Cascade

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002403